

## § 882.1410

to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

(b) *Classification*. Class II (performance standards).

### § 882.1410 Electroencephalograph electrode/lead tester.

(a) *Identification*. An electroencephalograph electrode/lead tester is a device used for testing the impedance (resistance to alternating current) of the electrode and lead system of an electroencephalograph to assure that an adequate contact is made between the electrode and the skin.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38807, July 25, 2001]

### § 882.1420 Electroencephalogram (EEG) signal spectrum analyzer.

(a) *Identification*. An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power spectral density of the electroencephalogram (EEG) signal.

(b) *Classification*. Class I (general controls).

[44 FR 51730-51778, Sept. 4, 1979, as amended at 66 FR 46953, Sept. 10, 2001]

### § 882.1430 Electroencephalograph test signal generator.

(a) *Identification*. An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38807, July 25, 2001]

### § 882.1460 Nystagmograph.

(a) *Identification*. A nystagmograph is a device used to measure, record, or

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visually display the involuntary movements (nystagmus) of the eyeball.

(b) *Classification*. Class II (performance standards).

### § 882.1480 Neurological endoscope.

(a) *Identification*. A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain.

(b) *Classification*. Class II (performance standards).

### § 882.1500 Esthesiometer.

(a) *Identification*. An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile sensitivity.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 65 FR 2319, Jan. 14, 2000]

### § 882.1525 Tuning fork.

(a) *Identification*. A tuning fork is a mechanical device which resonates at a given frequency and is used to diagnose hearing disorders and to test for vibratory sense.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, of this chapter, with the exception of § 820.180, with